

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
32nd CLINICAL TRIALS AND TRANSLATIONAL RESEARCH
ADVISORY COMMITTEE (CTAC) MEETING**

**Summary of Meeting
March 8, 2017**

Webinar

CLINICAL TRIALS AND TRANSLATIONAL RESEARCH ADVISORY COMMITTEE
WEBINAR
Summary of Meeting
March 8, 2017

The 32nd meeting of the Clinical Trials and Translational Research Advisory Committee (CTAC) of the National Cancer Institute (NCI) was held by webinar on Wednesday, March 8, 2017, at 11:02 a.m. The CTAC chair, Dr. Nancy E. Davidson, presided.¹ The meeting was adjourned at 1:30 p.m.

Chair

Nancy E. Davidson

CTAC Members

David F. Arons
Susan M. Blaney (absent)
Walter J. Curran, Jr.
David M. Gershenson
Michael L. LeBlanc
Patrick J. Loehrer, Sr.
David A. Mankoff
Edith P. Mitchell
Nikhil C. Munshi
Augusto C. Ochoa
Roman Perez-Soler
Gloria M. Petersen
Louis M. Weiner

Ad Hoc Members

Debra L. Barton
Janet E. Dancey
Timothy J. Eberlein (absent)
Howard J. Fingert
Paul A. Godley
Anne-Marie R. Langevin
Lynn M. Matrisian
Neal J. Meropol
Steven T. Rosen
Dan Theodorescu

Ex Officio Members

William L. Dahut, NCI (absent)
James H. Doroshov, NCI
Paulette S. Gray, NCI
Rosemarie Hakim, Centers for Medicare &
Medicaid Services
Michael J. Kelley, U.S. Department of Veterans
Affairs (absent)
Warren A. Kibbe, NCI
Richard Pazdur, U.S. Food and Drug
Administration (absent)

Executive Secretary

Sheila A. Prindiville, NCI

Presenters

Nancy E. Davidson, MD, Senior Vice President, Director and Full Member, Fred Hutchinson Cancer
Research Center
Toby T. Hecht, PhD, Acting Director for Pre-Clinical Research, Division of Cancer Treatment and
Diagnosis, NCI
Patrick J. Loehrer, Sr., MD, Director, Melvin and Bren Simon Cancer Center; Associate Dean for Cancer
Research, Indiana University School of Medicine
Douglas R. Lowy, MD, Acting Director, NCI

¹A roster of CTAC members and their affiliations is included as an appendix.

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I. Call to Order and Opening Remarks

Nancy E. Davidson, MD

Dr. Davidson called the 32nd meeting of CTAC to order and welcomed participants to the meeting. She introduced new ad hoc CTAC members—Drs. Meropol and Rosen.

Dr. Davidson reviewed the confidentiality and conflict-of-interest practices required of CTAC members during their deliberations. She invited members of the public to send written comments on issues discussed during the meeting to Dr. Prindiville within 10 days of the meeting. National Institutes of Health Events Management was videocasting the meeting, and the videocast would be available for viewing following the meeting at <http://videocast.nih.gov>.

Motion. A motion to accept the minutes of the 31st CTAC meeting held on November 2, 2016, was approved.

II. NCI Acting Director's Update

Douglas R. Lowy, MD

Dr. Lowy began his remarks by thanking CTAC members for their important work, which provides a tangible example of the ways in which the cancer research agenda continues to go forward despite current uncertainties.

NIH Visit by Members of Congress. In January 2017, the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, led by Representative Tom Cole (R-OK), visited NIH. Dr. Lowy and other NIH institute and center directors met subcommittee members during this visit. The visit also featured several patient demonstrations, including a patient with prostate cancer found through a directed biopsy technology developed at the Clinical Center. This patient was doing well 5 years after his treatment, and this technology, developed by Peter A. Pinto, MD, Investigator, Urologic Oncology Branch, NCI, and collaborators, has now been commercialized. This story is an excellent example of the application and dissemination of translational research in the clinic.

NIH Visit by Secretary of Health and Human Services Thomas E. Price, MD. Dr. Lowy met with Secretary Price during the secretary's recent NIH visit, when Dr. Lowy described the NCI Molecular Analysis for Therapy Choice (NCI-MATCH) trial as an example of a public-private partnership that is successfully accruing patients. Secretary Price clearly understood that this type of research could be done only through NIH. He also met a patient with metastatic breast cancer who had exhausted a variety of treatments. Steven A. Rosenberg, MD, PhD, Senior Investigator, NCI, and colleagues at the Clinical Center developed a T-cell-based treatment that targeted the molecular abnormality in the patient's tumor. The patient is now disease free, and Secretary Price was impressed with this result.

21st Century Cures Act. President Obama signed this bill into law in December 2016. As a result, NCI will receive slightly less than \$300 million in additional funds for research in fiscal year (FY) 2017. NCI will use these funds to support several Cancer Moonshot funding announcements (<https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/funding>).

NCI is establishing implementation teams for the Cancer Moonshot Blue Ribbon Panel (BRP) recommendations. These teams will help determine how best to spend the 21st Century Cures Act funds for FY 2018 and FY 2019. The teams will seek input from the BRP working groups, especially if they

consider plans beyond the BRP recommendations. For example, a recent workshop on Lynch syndrome resulted in several proposals not included in the BRP's recommendations that NCI might want to pursue, so the implementation team will discuss options with the appropriate BRP working groups. NCI plans to fund new research in FY 2017 that closely aligns with the BRP recommendations mostly through the aforementioned funding announcements. NCI will also hold a workshop featuring proposals for molecular analyses of specimens from completed clinical trials that could lead to important BRP-aligned research opportunities.

NCI's Annual Appropriation. NCI's annual appropriation supports an enormous amount of highly meritorious research. In fact, most of the clinical trials that CTAC reviews are supported through the annual appropriation and not the Cancer Moonshot. In addition, the annual appropriation funds the vast majority of NCI's investigator-initiated research as well as programs that recruit, train, and retain the best applicants. NCI is increasing the stipends for some of its physician training programs and the amounts for research funded through these programs. Finally, NCI uses its annual appropriation to support specific initiatives, including the RAS Initiative.

Questions and Discussion

Dr. Munshi asked whether the Moonshot funding is separate from NCI's annual appropriation. Dr. Lowy responded affirmatively, explaining that NCI will receive varying amounts of funding over the next 7 years for the Cancer Moonshot. This funding is not added to NCI's base funding, which comes through its annual appropriation. In 2024, when the Cancer Moonshot funding ends, the regular appropriation's purchasing power will decline more than 25 percent if it remains at its FY 2016 level.

Dr. Mankoff asked whether the Cancer Moonshot might support targeted investigator-initiated research in the future. Dr. Lowy said that NCI plans to offer additional targeted funding opportunities for investigator-initiated research in FY 2018 and 2019.

Dr. Langevin wondered whether the Cancer Moonshot funding could be cut in the future. Dr. Lowy explained that the future of this funding is uncertain. The House and Senate subcommittees have shown strong bipartisan support for sustained increases in funding for NIH, including NCI. Congress passed the 21st Century Cures bill with very strong bipartisan support, and Secretary Price voted in favor of the bill as a member of Congress. Dr. Lowy was optimistic that the funds from this act would continue to support NCI research.

Dr. Curran inquired how members of CTAC could effectively advocate on behalf of NCI. Dr. Lowy said that the best approach is to give members of Congress and other leaders information about the research opportunities in cancer and the progress that this research has made for patients. They can also point out that advances in cancer research are economic drivers in some sectors of the economy. Mr. Arons added that advocates on Capitol Hill are communicating about NCI's effectiveness under its current leadership. For example, NCI has established a goal of accelerating progress in cancer research under the Cancer Moonshot and has taken responsibility for a major component of the Precision Medicine Initiative. Congress needs to understand the importance of leveraging its previous investments, such as The Cancer Genome Atlas, because these activities are making progress. Furthermore, extramural funds support research in all 50 states, and funding for NCI provides critical resources to hospitals and laboratories in legislators' districts.

Dr. Lowy explained that in 2015, cancer was the only one of the top 10 causes of death in the United States for which mortality rates have continuously declined. This success is largely attributable to a better understanding of cancer and improved screening, prevention, and treatment approaches. However, the current rate of 600,000 deaths per year is still much too high.

Dr. Perez-Soler asked whether applications that address a BRP recommendation will receive preference for funding independently of priority scores. Dr. Lowy said funding for investigator-initiated research that aligns with BRP recommendations will still depend on the application's quality. More than ever, NCI is focusing on the quality of the science, the nature of the problem being addressed, and the likelihood that the proposed research will have a high impact.

III. National Clinical Trials Network External Evaluation Working Group Report

Patrick J. Loehrer, Sr., MD

The National Clinical Trials Network (NCTN) awarded its first 5-year grants in March 2014. In 2016, as NCI began considering the NCTN's renewal, CTAC formed the NCTN External Evaluation Working Group, chaired by Dr. Loehrer. The group's charge was to determine whether the NCTN's scientific contributions support continuing the program and, if so, to develop recommendations for enhancing the NCTN's scientific and operational functioning.

The group reviewed a list of trials that were activated since the start of the NCTN—the IND status, the registration trials, trials with translational studies, and trials with quality-of-life studies. They reviewed accrual of the trials by phase, by disease, and by grant year, cross-group accrual, and trial activation timelines. They also reviewed accomplishments from each NCTN group, a satisfaction survey of 307 group stakeholders, and group chairs' anonymous comments.

The working group has now completed a report (available at <https://deainfo.nci.nih.gov/advisory/ctac/0317/NEEwgReport.pdf>) in which it concluded that NCI should continue the NCTN program. The report notes that the program supports highly significant, practice-changing trials that could not be conducted without public funding. The report provides recommendations for the NCTN for each of four focus areas, highlighted below.

- Collaboration within the NCTN:
 - Enhance strategic scientific collaboration by NCTN groups and NCI
 - Maintain a high level of cross-group collaboration in accrual and study development
- Scientific impact:
 - Revise the NCTN goal statement to include text such as “reducing the morbidity and mortality of cancer for adults and children and improving patient outcomes”; eliminate the descriptors “randomized,” “definitive,” and “late phase”
 - Ask groups to identify areas of scientific excellence and expertise
- Efficiency:
 - Emphasize and facilitate accrual of minority/underserved participants
- External collaboration:
 - Highlight NCI's commitment to collaborations in NCTN trials with pharmaceutical and biotechnology companies, other federal programs, and international clinical trial groups

The report recommended future evaluation of the Integrated Translational Science Awards, the Imaging and Radiation Oncology Core credentialing standards, and the Lead Academic Participating

Centers, which were too new for the current evaluation. The report also recommended that CTAC analyze Scientific Steering Committee operating processes, the integration of translational research in NCTN studies, NCTN stakeholders' concerns regarding the number and type of NCTN trials, access to new agents and modalities, and the balance between the roles of the Cancer Therapy Evaluation Program and extramural investigators in the management of operational and scientific activities. CTAC should consider how to help community sites adapt to targeted phase II and precision medicine trials and conduct a comprehensive analysis of NCTN screening and accrual efficiency. Finally, the report recommended that NCI address concerns related to funding for patient screening and accrual, biospecimen collection, correlative studies, and support for the extra cost of registration trials.

Questions and Discussion

Minority Accrual. Dr. Weiner praised the working group for its very thorough review. The recommendations are based on sound logic and a thorough and knowledgeable evaluation. He noted that the report lists minority accrual as a challenge and asked about the dimensions of this issue and how the NCTN will identify and overcome barriers to minority recruitment. Dr. Loehrer replied that the report recommends that groups develop and share plans for facilitating minority accrual. For example, 46 percent of Hispanics in Indiana do not have health insurance, and they cannot enroll in clinical trials, because there is no way to cover the cost of care outside a trial. This type of issue is difficult to address in isolation.

Dr. Munshi, a member of the working group, added that the working group's plan was to ask the NCTN groups to develop strategies to address barriers in their own environments. If they need more funding or other resources to implement these strategies, they should request these resources in their applications. Dr. Weiner suggested that the groups partner with sponsors to lower barriers to accrual based on eligibility criteria.

Dr. Perez-Soler asked about the proportion of NCTN trial participants from minority populations and suggested setting a realistic target for accruing minority patients for the next NCTN funding period. Meg Mooney, MD, MBA, Chief, Clinical Investigations Branch, NCI, said that approximately 15 percent of patients in NCTN trials are not white. This proportion has increased over time, and the emphasis on minority accrual will continue in the NCTN renewal. Dr. Perez-Soler pointed out that minorities make up 20 percent to 25 percent of the U.S. population, and a 15 percent rate is better than he had expected.

Dr. Ochoa said that because many minority patients come from community sites, one way to increase their accrual is to involve these sites in designing trials. Trials designed by highly specialized centers often include requirements that community sites cannot meet. Increased funding would also facilitate minority participation in NCTN trials. Minority patients are eager to enroll in clinical trials, but stringent study requirements prevent many community sites from enrolling them.

Dr. Mitchell suggested that the NCTN groups conduct research on barriers to minority accrual and how to facilitate minority participation. Population-based research might provide insight into the reasons for low participation rates, given the interest of many minority patients in clinical trials. Dr. Barton commented that the Symptom Management and Health-Related Quality of Life Steering Committee has a minority expert who identified eligibility criteria in several trials that would have been unduly biased against minority recruitment. She also supported a systematic evaluation of the barriers to minority recruitment across NCTN sites and studies to provide insights into the types of eligibility criteria that could facilitate minority recruitment.

Worta McCaskill-Stevens, MD, MS, Chief, Community Oncology and Prevention Trials Research Group, NCI, said that minorities make up approximately 23 percent of participants in NCTN and NCI Community Oncology Research Program (NCORP) studies. NCI has examined barriers to enrollment and has several activities aimed at overcoming these barriers, and a new working group representing all NCTN groups will develop cancer disparity research questions and common strategies for addressing barriers. Dr. Loehrer suggested that the Patient Protection and Affordable Care Act, which increased access to health insurance, probably increased minority accrual to NCTN and NCORP trials.

Collaboration. Dr. Weiner approved of the recommendation for the NCTN groups to develop core areas of expertise. Dr. Loehrer noted, as an example, that the ECOG-ACRIN Cancer Research Group has unique expertise in imaging, and another group might have unique genomic or pharmacogenomic proficiency or experience successfully recruiting minorities to clinical trials. Dr. Munshi added that knowing the types of expertise of each group will help them identify suitable NCTN collaborators.

Dr. Theodorescu asked about interaction between the NCTN and the Specialized Programs of Research Excellence (SPOREs), as well as plans to centralize tissue repositories or create common databases that help investigators find NCTN tissues to use for their studies. He also asked about interactions between the NCTN and the NCORP. Dr. Hecht planned to address the question about SPOREs in her presentation later in this teleconference. She did note, however, that the SPOREs conduct early translational research, and they are encouraged to hand off their completed research to the NCTN. Dr. Loehrer explained that many NCTN institutions are reluctant to share tissue, but sharing tissue specimens is important, and several NCORP sites are already doing so. Annotating all NCTN tissue specimens provides information on side effects and long-term outcomes.

NCTN Goal. Dr. Petersen said that the proposed changes to the NCTN goal would make the goal statement overly general and less informative. Dr. Loehrer explained that in addition to the proposed wording changes, NCI should indicate that the NCTN supports innovative phase II trials and impactful phase III trials. A concern is that the original goal statement treats patients like subjects, and it does not mention reducing the burden of cancer on patients. The working group suggested eliminating the term “late phase,” because the NCTN’s randomized phase II trials are not necessarily late phase.

Dr. Matrisian noted that fewer than half the stakeholders surveyed by the working group indicated that the number and “menu” of NCTN trials met expectations. She suggested that NCI give more thought to what the program is trying to accomplish and making sure that the community understands the program’s objectives.

Motion. A motion carried to accept the report of the NCTN External Evaluation Working Group.

IV. Board of Scientific Advisors/National Cancer Advisory Board Specialized Program of Research Excellence Working Group Report

Toby T. Hecht, PhD

In 2014, NCI formed the Board of Scientific Advisors (BSA)/National Cancer Advisory Board (NCAB) Specialized Program of Research Excellence (SPORE) Working Group. The group’s charges included assessing the SPORE program’s continued value for NCI, whether NCI still needs a program that emphasizes translational research, and whether NCI should continue the program. The working group

completed a report (<https://deainfo.nci.nih.gov/advisory/bsa/workGroup/spore/BSA-NCAB-SPORE-Evaluation-WG-Final.pdf>) in 2016 with recommendations for both NCI and the SPORE program.

Dr. Hecht asked CTAC to focus on the SPORE program recommendations that are not currently being implemented, and explained NCI's proposed responses:

- Re-brand the SPORE program as the Translational Research Excellence (TREN) program.
 - After weighing the pros and cons of changing the name, NCI plans to retain the SPORE moniker.
- Eliminate the requirement for a minimum number of projects within each grant to facilitate development of both small focused projects and large-scale team-based projects.
 - For all new SPORE applications, three projects (rather than four) is being proposed as the minimum number required for submission.
 - For competing renewal applications, NCI is proposing the option of a minimum number of two projects. These applicants may expand two successful projects from the prior funding period.
- Require at least one—but not all—translational research projects to incorporate a defined clinical endpoint.
 - NCI proposes requiring a clinical trial or population study for at least one scientific project in each SPORE as a means of strengthening the translational aspect of the program.

One issue that arose at the BSA/NCAB discussion of the report on December 6, 2016, is whether the SPORE program should require early detection, prevention, and population science (EPPS) projects or whether the current incentive (up to \$200,000 for one or more EPPS projects) is sufficient. A second issue was whether to use direct costs instead of total costs for the funding cap.

After CTAC offers its feedback on the report, the next steps toward renewal of the SPORE program announcement will be reviews by the Clinical and Translational Research Operations Committee and Scientific Program Leadership Committee.

Questions and Discussion

Dr. Gershenson, a SPORE project leader, congratulated Dr. Hecht and the working group on the excellent report. He agreed with the recommendation to reduce the required number of SPORE projects from four to three. Often, the fourth project is not strong, and a minimum of two projects would be too low. He also agreed with the recommendations to preserve the human endpoint requirement in all SPORE projects and not to change the program's name. He thought that incentives were better than mandates for EPPS projects, but even incentives should be eliminated because some groups are not strong in EPPS research. Dr. Gershenson also agreed with the recommendation to encourage multi-institutional research projects, which is one of the charges of the Cancer Moonshot, although he suggested strengthening this recommendation. He supported a recommendation to increase the integration, leveraging, and interfacing of current NCI translational programs with industry, advocacy groups, and other funding agencies. Collaboration between the SPORE program and the National Clinical Trials Network is particularly important. Finally, Dr. Gershenson supported a recommendation to continue the SPORE program's Career Enhancement Program activities.

Cap on Direct vs. Total Costs. Dr. Petersen, a SPORE principal investigator, agreed with the proposal to base the funding cap on direct costs only and not total costs, because of a possible chilling effect on interinstitutional collaborations.

Minimum Number of Projects. Dr. Peterson agreed with the recommendation to require a minimum of three projects for each SPORE. However, she argued against the recommended minimum of two projects for competing renewal applicants, because two projects are too few and a minimum of three projects for all applicants is simpler and easier. Dr. Theodorescu agreed with Dr. Petersen's recommendation to require all SPORE applications to include at least three projects, which would prevent PIs from narrowing the focus of their research excessively. Dr. Perez-Soler also favored the recommended three-project minimum, because it would open the program to more cancer centers.

Dr. Davidson agreed that a minimum of three projects for all SPORE applicants, including competing renewal applicants, makes sense. An argument in favor of a two-project minimum for competing renewals is that it takes a long time to develop research that is translationally and clinically important. However, such a minimum would allow investigators to continue the same research. One of the advantages of the SPORE program is that it encourages fresh and successful ideas that can be transferred to other settings.

Dr. Matrisian favored a two- or even one-project minimum for competing renewals because of the complexity of translating research results and the many barriers to moving discoveries through the entire developmental pathway and into practice. Too often, smaller projects go nowhere, so a small number of larger projects might have a greater chance of making it "across the finish line." Dr. Theodorescu suggested allowing competing renewals to include two projects for one renewal cycle only. Dr. Petersen said that if a project is truly compelling, its investigators can find other sources of funding or a clinical trials group to take on the project. The SPORE program focuses on early-phase translational research.

Dr. Munshi, also a SPORE project leader, supported the proposed three-project minimum, because a purpose of the SPORE program is to develop translational scientists. The program focuses on early-phase studies, and subsequent studies are done by larger groups. Dr. Mitchell also agreed, suggesting that three projects have greater potential impact and chance to enhance the growth of younger investigators than two projects. Dr. Gershenson added that the benefits of a smaller number of projects (e.g., focusing the enormous effort required for translational research) do not outweigh the benefits of the diversity offered with three projects.

SPORE Program Name. Dr. Theodorescu argued against changing the program's name. He suggested that, at most, NCI change the program's name minimally, such as to the Special Programs of Research Translation (SPORT).

Multi-institutional Collaboration. Dr. Hecht reported that 62 percent of funded SPOREs involve more than one institution, and many include three or four. The proportion used to be approximately 20 percent, so NCI's approach here has been successful. Changing the funding cap to direct costs only is likely to increase this proportion further. Dr. Petersen supported the call to encourage interinstitutional collaborations.

Animal Studies. Dr. Theodorescu asked whether the proposed requirement for clinical endpoints is intended to pertain only to clinical trials or whether it could extend to studies of animals. Dr. Hecht

explained that NCI encourages the inclusion of animals in SPORE projects, but these studies are translational only if they include human specimens to study a clinical observation in cancer patients or populations at risk of cancer. The requirement for human endpoints has been part of the SPORE program since its inception, and the recommendation is to keep this requirement. Many other funding mechanisms support studies in animal models.

Expanding SPORE Focus Areas. Dr. Munshi inquired about recommendations to create SPOREs that focus on biological factors, such as genes associated with several cancer sites. Dr. Hecht replied that NCI encourages applicants to submit these types of SPORE applications, and NCI is likely to support several new types of SPOREs in the future. Dr. Perez-Soler asked whether the working group considered encouraging applicants to propose precision medicine SPOREs based on certain targets. Dr. Hecht said that NCI funds a pediatric hyperactive RAS SPORE.

Proposed Clinical Endpoint Requirement. Dr. Mankoff agreed with the clinical trial recommendation, which could give incentives to SPOREs to work with a clinical trials group or plan to hand their research over to such a group. Dr. Hecht said that some SPOREs use NCI National Clinical Trials Network (NCTN) specimens in their correlative studies, and some SPOREs hand their projects off to the NCTN. Dr. Hecht would like to find ways to make these transitions between the SPOREs and the NCTN smoother and more efficient. Dr. Mankoff suggested that NCI indicate that SPORE review panels will consider collaborations with clinical trial groups.

Dr. Dancey noted that other clinical research (beyond clinical trials) can have clinical endpoints, and not all clinical trials have clinical endpoints. Dr. Hecht said that NCI has not required SPOREs to include a clinical trial, but they were required to include a human endpoint. The question is whether to require that at least one project “go all the way to the clinic.” Every SPORE currently has at least one clinical trial, and requiring SPOREs to conduct clinical trials would add to the program’s translational goals.

Drs. Munshi and Davidson questioned the need for the proposed requirement, given that all funded SPOREs have included a clinical trial. Dr. Hecht explained that the BSA/NCAB working group made this recommendation, and the fact that it is already happening shows that the recommendation is feasible. Dr. Petersen agreed with the idea of making the current practice more formal and requiring at least one project to have a clinical endpoint. She also noted that other projects must have a human endpoint, which she also supports.

EPPS Projects. Dr. Petersen pointed out that EPPS projects involve human endpoints and can involve population-level clinical trials. She supported the incentive for EPPS projects, which she thought was a better approach than requiring all SPOREs to have an EPPS project.

V. Ongoing and New Business

Nancy E. Davidson, MD

Legislative Update

Dr. Prindiville encouraged CTAC members to review the legislative update in the meeting materials. This update was prepared by M.K. Holohan Quattrocchi, JD, Director, Office of Government and Congressional Relations, NCI.

Working Group Updates

Dr. Prindiville provided updates on CTAC's working groups:

- National Clinical Trials Network External Evaluation Working Group (chair: Dr. Loehrer)—Has completed its work
- Clinical Trials Informatics Working Group (co-chairs: Drs. Kibbe and Weiner)—Met in person in November 2016; has several subgroups that have been meeting since November; expected to provide an update at the July 2017 CTAC meeting
- Progress in Small-Cell Lung Cancer Research Working Group (chair: Charles Rudin, MD, PhD, Weill Cornell Medical College)—Identified initiatives that have led to NCI funding opportunity announcements; will monitor progress in funded programs; expected to reconvene in early 2018
- Pancreatic Ductal Adenocarcinoma Progress Working Group (chair: James Abbruzzese, MD, Duke University)—Identified initiatives that have led to NCI funding opportunity announcements; will monitor progress in funded programs; expected to reconvene later in 2017
- Clinical Trials Strategic Assessment Working Group (chair: to be determined)—Will assess the strategic clinical trials priorities established by the Scientific Steering Committees, evaluate the quality and objectivity of individual strategic clinical trial portfolio assessments by the Scientific Steering Committees, conduct a cross-portfolio assessment; hope to name a chair and members by the July 2017 CTAC meeting

Dr. Davidson proposed that CTAC form a small group to help her and the Coordinating Center for Clinical Trials set agendas for CTAC meetings in the future. This group could identify emerging issues and prioritize potential agenda items. Dr. Prindiville encouraged CTAC members to contact her and Dr. Davidson if they are interested in joining the Clinical Trials Strategic Assessment Working Group or the agenda-setting group.

VI. Adjournment

Nancy E. Davidson, MD

There being no further business, the 32nd meeting of CTAC was adjourned at 1:30 p.m. on Wednesday, March 8, 2017.

Appendix

National Institutes of Health National Cancer Institute Clinical Trials and Translational Research Advisory Committee

CHAIR

Nancy E. Davidson, MD 2018
Senior Vice President, Director and Full Member
Clinical Research Division
Fred Hutchinson Cancer Research Center
President & Executive Director
Seattle Cancer Care Alliance
Head
Department of Medicine
Division of Medical Oncology
University of Washington
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MEMBERS

David F. Arons, JD (NCRA) 2017 Chief Executive Officer National Brain Tumor Society Watertown, MA	Walter J. Curran, Jr., MD, PhD 2019 Professor and Chairman Department of Radiation Oncology Emory University School of Medicine Atlanta, GA
Debra L. Barton, PhD, RN 2021* Mary Lou Willard French Professor of Oncology Nursing University of Michigan School of Nursing Ann Arbor, MI	Janet E. Dancey, MD 2021* Professor Department of Oncology Director Canadian Cancer Trials Group Queen's University Kingston, Ontario, Canada
Susan M. Blaney, MD 2019 Vice President for Clinical and Translational Research Vice Chair for Research Department of Pediatrics Baylor College of Medicine Texas Children's Hospital Texas Medical Center Houston, TX	Timothy J. Eberlein, MD 2020* Bixby Professor and Chairman Department of Surgery Washington University School of Medicine St. Louis, MO
	Howard J. Fingert, MD 2020* Senior Medical Director Millennium: The Takeda Oncology Company Cambridge, MA

David M. Gershenson, MD Professor of Gynecology Department of Gynecologic Oncology and Reproductive Medicine Division of Surgery MD Anderson Cancer Center University of Texas Houston, TX	2020	Patrick J. Loehrer, Sr., MD Director Melvin and Bren Simon Cancer Center Associate Dean for Cancer Research Indiana University School of Medicine Indianapolis, IN	2020
Paul A. Godley, MD, PhD, MPP Executive Associate Dean for Faculty Affairs Professor of Hematology/Oncology University of North Carolina Chapel Hill, NC	2021*	Lynn M. Matrisian, PhD, MBA Chief Research Officer Pancreatic Cancer Action Network Washington, DC	2021*
Anne-Marie R. Langevin, MD Greehey Distinguished Chair in Pediatric Oncology University of Texas Health Science Center San Antonio, TX	2021*	Neal J. Meropol, MD Dr. Lester E. Coleman, Jr., Professor of Cancer Research and Therapeutics Department of Medicine Associate Director for Clinical Research Case Comprehensive Cancer Center University Hospitals Cleveland Medical Center Case Western Reserve University Cleveland, OH	2021*
Michael L. LeBlanc, PhD Member Fred Hutchinson Cancer Research Center Research Professor Department of Biostatistics University of Washington Seattle, WA	2019	Nikhil C. Munshi, MD Associate Director Jerome Lipper Multiple Myeloma Center and LeBow Institute for Myeloma Therapeutics Dana-Farber Cancer Institute Professor of Medicine Harvard Medical School Boston, MA	2018
David A. Mankoff, MD, PhD Gerd Muehlelehner Professor of Radiology Chief of Nuclear Medicine and Clinical Molecular Imaging Perelman School of Medicine University of Pennsylvania Philadelphia, PA	2019	Augusto C. Ochoa, MD Director Stanley S. Scott Cancer Center Professor Department of Pediatrics Louisiana State University Health Sciences Center New Orleans, LA	2018
Edith P. Mitchell, MD Associate Director for Diversity and Minority Programs Sidney Kimmel Comprehensive Cancer Center at Jefferson Clinical Professor of Medicine and Medical Oncology Thomas Jefferson University Philadelphia, PA	2018		

<p>Roman Perez-Soler, MD (BSC) Professor and Chairman Department of Oncology Montefiore Medical Center Deputy Director Albert Einstein Cancer Center Director Division of Medical Oncology Albert Einstein College of Medicine Bronx, NY</p>	<p>2020</p>	<p>Dan Theodorescu, MD, PhD Professor and Director University of Colorado Cancer Center Aurora, CO</p>	<p>2020*</p>
<p>Gloria M. Petersen, PhD Professor of Epidemiology Department of Education Administration Mayo Clinic College of Medicine & Science Rochester, MN</p>	<p>2019</p>	<p>Louis M. Weiner, MD (BSC) Director Lombardi Comprehensive Cancer Center Francis L. and Charlotte G. Gagnani Chair Department of Oncology Georgetown University Medical Center Washington, DC</p>	<p>2017</p>
<p>Steven T. Rosen, MD Provost, Chief Scientific Officer, and Director Comprehensive Cancer Center and Beckman Research Institute Irell & Manella Cancer Center Director's Distinguished Chair Comprehensive Cancer Center City of Hope Duarte, CA</p>	<p>2021*</p>		

*Pending Appointment

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